10

15

42

CLAIMS:

- 1. A biological suspension processing system comprising:
- a suspension treatment device for treating one or more components of a biological suspension;
 - a first fluid flow path communicating with the treatment device for introducing a suspension into the treatment device;
 - a second fluid flow path communicating with the treatment device for withdrawing a constituent of the suspension from the treatment device; and
 - at least one microelectromechanical sensor communicating with one of said fluid flow paths for sensing a selected characteristic of the fluid within the flow path.
- The system of claim 1 in which a sensor senses one 2. ormore characteristics selected from the group consisting of flow rate, pH, cell cell type, antigenicity, cell concentration, cell count, viscosity, 20 cholesterol, hematocrit, DNA, viral orbacterial presence, pathogen presence, and partial pressure of a selected gas.
- 25 3. The system of claim 1 in which a sensor communicates with the first fluid flow path and generates a signal responsive to one or more selected characteristic of the fluid in the first fluid flow path, the suspension treatment device including a controller adapted to

anilla Hrasil Brasil

11,

tj

lle is

2.0 2.4 2.4

Shuff House

15

20

30

receive the sensor signal and to control the treatment device in response thereto.

- 4. The system of claim 1 in which a sensor communicates

 5 with said second fluid flow path and generates a signal
 responsive to a selected characteristic of the fluid in
 the second fluid flow path, the suspension treatment
 device including a controller adapted to receive the
 sensor signal and to control the treatment device in

 10 response thereto.
 - 5. The system of claim 1 in which the sensor is adapted to sense the selected characteristic a plurality of times at discrete intervals.
 - 6. The system of claim 5 in which the sensor generates a signal responsive to a selected characteristic of the fluid in the flow path, the suspension treatment device including a controller adapted to receive the sensor signal and to control the treatment device in response thereto.
- The system of claim 6 in which sensor communicates with the second fluid flow path and senses the
 approximate quantity or concentration of a selected cell.
 - 8. The system of claim 1 further comprising a container communicating with the second fluid flow path for receiving the withdrawn constituent, the system being adapted to provide tracking information for associating

15 ·

44

with the container the particular characteristic sensed by at least one sensor.

- 9. The system of claim 8 in which the system comprises
 5 machine readable or human readable data storage media
 carried by the container, the data storage media storing
 information regarding the particular characteristic
 sensed by at least one sensor.
- 10 10. The system of claim 9 in which the data storage media comprises a bar code label on the container.
 - 11. The system of claim 9 in which the data storage media comprises an electronic data storage device.
 - 12. The system of claim 11 in which the electronic data storage device has a non-volatile semiconductor memory.
- 13. The system of claim 9 in which the data storage
 20 media comprises at least one icon carried by the
 container and representative of the sensed
 characteristic.
- 14. The system of claim 9 in which the suspension includes one or more blood components and the blood component withdrawn is a cellular component, and the container is for storing the cellular component withdrawn, and the data storage media includes data regarding the type, quality, purity, quantity or

WO 02/05059 PCT/US01/21188

45

concentration of the cellular blood component in the container.

The system of claim 1 in which the at least one sensor includes a first sensor communicating with the first fluid flow path and a second sensor communicating with the second flow path and the treatment device comprises an apheresis device and the comprises whole blood, the first sensor sensing platelets determine a platelet count in the suspension introduced into the apheresis device and the second sensor sensing platelets to determine a platelet count in the second flow path, wherein the system includes a container communicating with the second flow path for storing blood platelets withdrawn, and the system further comprises machine readable or human readable data storage media carried by the container, the data storage media storing information regarding platelet count sensed by one or both of said sensors.

20

25

15

5

10

and man

.

E Coj

ļ.,

The state of

The system of claim 1 in which a sensor communicates with said second fluid flow path, and said system for storing the constituent includes a container withdrawn, the sensor generating a signal responsive to a characteristic of the constituent withdrawn, and the system includes a data recording device for receiving the signal and recording data regarding the sensed characteristic of the constituent withdrawn.

- 17. The system of claim 16 in which the data recording device comprises a printer for printing a report of the characteristic sensed.
- 5 18. The system of claim 17 in which the report is in machine readable graphic format.

10 H

ļ.

affa than

10 mm

ordin is district.

71)

25

- 19. The system of claim 16 wherein the container carries a machine readable electronic data storage device, and in which the data recording device is adapted to transfer data regarding the selected characteristic sensed by the sensor to the electronic data storage device.
- 20. The system of claim 19 in which the electronic 15 storage device comprises a non-volatile semiconductor memory.
- 21. A disposable plastic blood component storage container defining an interior compartment for receiving 20 a blood component, and at least one microelectromechanical sensor carried by the container and communicating with the compartment for sensing a selected characteristic of the blood component received therein.

22. The container of claim 21 in which the sensor is adapted to sense bacterial presence or pH in the blood component just before it is administered to a patient.

10

15

25

47

- 23. The container of claim 21 in which the sensor includes write once, read many times data storage, and is adapted to be read by an automated reading device.
- 5 24. A blood processing system for providing a characterized blood constituent product, the system comprising:

an apheresis device for separating one or more desired cellular blood constituents from a suspension comprising whole blood;

- a first fluid flow path communicating with the apheresis device for introducing a suspension comprising whole blood into the device;
- a second fluid flow path communicating with the apheresis device for withdrawing at least one desired cellular blood constituent from the device;
- a container communicating with the second fluid flow path for receiving the blood constituent withdrawn from the apheresis device;
- 20 machine readable or human readable data storage media carried by the container;
 - at least one microelectromechanical sensor communicating with the first fluid flow path for sensing at least one characteristic of the whole blood and for generating at least one electrical signal responsive to said sensing;
 - at least one microelectromechanical sensor communicating with the second flow path for sensing the quantity of cellular blood constituent withdrawn from the

5

Tank days

å på

FU)

ļ.

17.0 11 mpr.

Find,

25

apheresis device and for generating an electrical signal responsive to said sensing;

a data recorder adapted to receive the electrical signals from the sensors and to record data regarding the sensed characteristics on the data storage media, whereby a user may readily identify the sensed characteristic regarding the whole blood and the quantity of the desired cellular constituent in the container.

- 10 25. The system of claim 24 including а sensor communicating with the second fluid flow path for sensing the quantity of a non-desired biologic constituent in the flow path and generating an electrical signal responsive to the amount, the data recorder being adapted to receive such signal and record data regarding the quantity of 15 non-desired cellular constituent in the data storage media for access by a user of the product in the container.
- 20 26. The system of claim 25 in which the non-desired biologic component is a viral constituent.
 - 27. The system of claim 25 in which the non-desired biologic component is a cellular constituent.
 - 28. The system of claim 27 wherein the desired cellular blood constituent is platelets or red cells and wherein the non-desired cellular constituent is white cells.

WO 02/05059 PCT/US01/21188

29. The system of claim 24 further comprising a controller adapted to receive the signals from the sensors communicating with the first and second fluid flow paths and to control the apheresis device in response to one or more of such signals to provide a desired cellular blood constituent product characterized by data recorded in the data storage media in accordance with characteristics sensed by the sensors.

5

₽»:

drest dest met

ļ, p. la

li sia

Fig.

The state of the

IJ

20

25

- 10 30. The system of claim 29 in which the desired cellular blood constituent is platelets, red cells, stem cells or white cells.
- 31. The system of claim 24 in which the data storage media comprises machine readable graphics carried on the container.
 - 32. The system of claim 31 in which the machine readable graphics comprises a bar code.
 - 33. The system of claim 24 in which the first fluid flow path communicates with the vascular system of a human donor, and the system includes means for generating a human-readable report for the donor containing selected data regarding one or more of the sensed characteristics.
 - 34. A biological suspension processing system comprising:
- a blood treatment device for treating one or more components of a biological suspension;

a human subject;

5

10

15

20

ndle their furt

Į,

Hanna An

H.

###

la.

ļ. Pozļa

Fi,

a first fluid flow path communicating with the vascular system of the human subject and the treatment device for introducing blood from the human subject into the treatment device;

a second fluid flow path communicating with the treatment device for withdrawing a constituent of the blood from the treatment device;

a third fluid flow path communicating with the treatment device from withdrawing another constituent of the blood from the treatment device; and

at least one microelectromechanical sensor communicating with one of said fluid flow paths for sensing a selected characteristic of the fluid within the flow path.

- 35. The system of claim 34 in which the sensor generates a signal responsive to one or more selected characteristic of the fluid in one of the fluid flow path, the suspension treatment device including a controller adapted to receive the sensor signal and to control the treatment device in response thereto.
- 36. The system of claim 35 in which the third fluid flow path communicates with the human subject, the treatment device is adapted to add anticoagulant to the blood in the first fluid flow path, the selected characteristic includes the hematocrit of blood in the first fluid flow path, and the controller controls the addition of anticoagulant into the first fluid flow path.

in i

25

5

- 37. The system of claim 35 in which the controller controls the treatment device in response to the signal to avoid one or more deleterious consequences to the human subject.
- 38. The system of claim 35 in which the controller controls the treatment device in response to the signal to withdraw a constituent of desired quality.
- 10 39. The system of claim 35 in which the controller controls the treatment device in response to the signal to withdraw a constituent of desired quantity.
- 40. The system of claim 35 in which the control controls
 15 the treatment device in response to the signal to
 withdraw a constituent that is depleted of an undesired
 component.
- 41. The system of claim 40 in which the undesired 20 component is white cells.
 - 42. The system of claim 35 in which the controller controls the treatment device in response to the signal to withdraw a desired constituent.
 - 43. The system of claim 42 in which the desired constituent is platelets.

- 44. The system of claim 42 in which the desired constituent is red cells or plasma.
- 45. The system of claim 35 in which the sensor senses platelets and the controller controls the treatment device to withdraw a selected minimum quantity of platelets.